510(k) SUMMARY

DEC 2 2 2006

SUBMMITTER:

SpineCraft
2215 Enterprise Drive
Westchester, IL 60154-5819

CONTACT PERSON: Ami Akallal-Asaad, Regulatory Affairs Manager

DATE PREPARED: November 02, 2006

CLASSIFICATION NAME: Spinal Interlaminal Fixation Orthosis - 888.3050
Spinal Pedicle Fixation - 888.3070(b)(1)

PROPRIETARY NAME: APEX Spine System

COMMON NAME: Spinal Fixation System

PRODUCT CODE: KWP, MNH, MNI

CLASSIFICATION PANEL: 87

PRODUCT DESCRIPTION: The APEX Spine System is a rod-based system designed to interface with various spinal anatomies. The system consists of spinal rods, monoaxial screws, polyaxial screws, bolt-type pedicle screws, various lateral connectors, and various cross (transverse) connectors.

MATERIALS: The APEX Spine System is manufactured from implant grade titanium Alloy (Ti-6Al-4V) conforming to ASTM standard F-136 and ISO 5832-3.

INDICATIONS FOR USE: The APEX Spine System intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

The APEX Spine System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The APEX Spine System is also a hook and sacral/iliac screw fixation system of the non-cervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudo-arthrosis).

The APEX Spine System when used with pedicle screws are indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

SUBSTANTIAL EQUIVALENCE:

The APEX Spine System is substantially equivalent to the following predicate devices:

- MONARCH Spine System: K010576, K024348 - DePuy AcroMed.
- MOSS MIAMI Spinal System: K965145 - DePuy, Inc.
- OPTIMA Spinal System: K051971 - U&I Corp.
- Global Spinal Fixation System: K001668 - D.K.M. Co., Ltd.

The substantial equivalence of the APEX spine system to the above mentioned predicate devices is based upon equivalence in design, material, manufacturing standards, intended use, as well as indications and contraindications. The fundamental scientific technology of this system is identical to previously cleared systems.

PERFORMANCE DATA:

Mechanical and dynamic testing of the APEX Spine System was performed. The test results demonstrate that the mechanical performance of the APEX Spine System is at least comparable to, if not better than, those of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SpineCraft, Inc.
% Ms. Ami Akallal-Asaad
Regulatory Affairs Manager
2215 Enterprise Drive
Suite 1504
Westchester, Illinois 60154

DEC 2 2 2006

Re: K062513
Trade/Device Name: APEX Spine System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, KWQ, MNI, MNH
Dated: November 2, 2006
Received: November 6, 2006

Dear Ms. Akallal-Asaad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. Indication for Use Statement

510(k) Number (if known): K062513

Device Name: APEX Spine System

Indication for Use:

The APEX Spine System intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

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Prescription Use: ___x___ AND/OR Over-The-Counter Use: _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruhlow

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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